Quick Reference Guide for IRB submission at Air Command and Staff College

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14. ABSTRACT
The purpose of this guide is to create a quick reference to Institutional Review Board (IRB) submission for Air Command and Staff College (ACSC) students. The challenge that most students face who are interested in doing research at ACSC is that there is no on-site IRB. In order to submit an IRB for research consideration, there are many factors that will need to be considered. These include determining whether human research will be conducted, if an expedited review can be submitted, investigator training requirements and funding issues. An IRB submission example is included to guide the reader in the IRB process.

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AU/ACSC/THARP/2009

AIR COMMAND AND STAFF COLLEGE

AIR UNIVERSITY

ACSC EEG BASELINE ASSESSMENT

by

David F. Tharp, Maj, USAFR

A Research Report Submitted to the Faculty

In Partial Fulfillment of the Graduation Requirements

Advisor: Colonel Brett Morris

Maxwell Air Force Base, Alabama

April 2009

Disclaimer

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Contents

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I would like to take this time to acknowledge Dr. Brett Morris for his incredible tenacity for research as well as guidance on the creation of this product. I have never met a man whose knowledge and expertise (currently a Ph.D and six Masters Degrees) is as diverse or who continues the legacy of true spirituality with integrity. I would also like to thank Sophie Ryan who was extremely helpful in coordinating a professional relationship with the Wright Patterson AFB IRB. Substantial help was also provided by Lt Col Scott Rodgers at AFRL in preparation for the IRB submission. Finally, the author is greatly indebted to his wife, Katherine Ann Tharp, who was extremely patient with my educational endeavors as she continued her pre-med coursework in the midst of taking care of our two beautiful little boys, Joshua (age 2) and Peyton (age 1).

AU/ACSC/05-2539/2008-09

Abstract

The purpose of this guide is to create a quick reference to Institutional Review Board (IRB) submission for Air Command and Staff College (ACSC) students. The challenge that most students face who are interested in doing research at ACSC is that there is no on-site IRB. In order to submit an IRB for research consideration, there are many factors that will need to be considered. These include determining whether human research will be conducted, if an expedited review can be submitted, investigator training requirements and funding issues. An IRB submission example is included to guide the reader in the IRB process.

Welcome to the world of research at Air University (AU)! Choosing the type of research, whether it be historical (ex post facto), current or longitudinal, is key while at Air Command and Staff College (ACSC). Most research at AU is historical in nature. The purpose of this paper is to guide the researcher who is interested in using the scientific method for current or longitudinal study that requires Institutional Review Board (IRB) approval. Research at Air University provides a wealth of subjects that you will most likely not find at many universities or in other research populations.

The opportunity to perform research while at ACSC will be a daunting task, not because of willing subjects, but most likely due to time constraints, the IRB process, and the need to de-conflict with Air University Instructions (AUI). This guide will help you navigate the IRB maze. IRB's are important because they protect human subjects. If you are going to utilize human subjects in your research, then proper procedures must be followed. The Air Force takes great pride in ensuring that proper procedures are addressed to ensure ethical guidelines are followed.

Air University Instruction (AUI) encourages researchers to review the requirements for IRB submission and provides guidance as to how this should be done. Unfortunately, what is required by the Wright-Patterson Air Force Base (WPAFB) IRB and what is recommended by AFI 40-402 are similar but not exactly synonymous. For example, in Attachment 3 of the AFI 40-402, the sample format, protocol for human research, does not provide an IRB checklist, indicate the need for a division cover letter, provide an example memorandum for the IRB, background information, electronic submission of specified documents, or references. Although much of the information is similar, the AFRL IRB provided much more detail as to what they required and how the specific information should be formatted. The AFRL IRB provided a much more elaborate informed consent than the sample found in attachment 4 of the AFI 40-402.

It is the recommendation of this author to contact the IRB to whom you will be submitting your protocol and follow their guidance for IRB submission. This will essentially de-conflict any inconsistencies and help guide you with specific examples for your IRB protocol. This guide follows the AFRL IRB guidance and provides a step-by-step approach to creating an IRB protocol so that you can complete your research within the time frame allotted.

One of the biggest challenges in regards to research at ACSC is time. In order to do research with human subjects, you will have to obtain IRB approval very early in the process. Unfortunately, even with an expedited review request, you will have to create and submit a complete and full IRB proposal. Most IRB's will meet once a month. For example, the WPAFB IRB meeting, which is most likely the one you will need for submission, is usually the third Thursday of the month. There are multiple requirements such as Collaborative Institutional Training Initiative (CITI) training that you will have to complete prior to submission of the IRB. This guideline will help you process the requirements based on a six-step approach and help streamline the process.

Six Step Process

Step 1: Coordinate your proposal with the ACSC Research Director

You will need to come to agreement on the content of your research, whether or not your research meets the criteria for human subjects testing, and finding ways to keep your research feasible given the time constraints of ACSC. The content of your research will probably start out larger than what you are able to accomplish at ACSC. Clinical research often takes years to complete. Remember, your research will need to be complete by January so time is of the essence. Therefore, it is imperative that you limit your research to that which is actually doable.

When you begin to involve human subjects, this exacerbates the challenge due to confidentiality issues, demographic information, informed consent, etc. Human subject's research at ACSC should be closely coordinated with the ACSC director of research. The contact information for the director of research at ACSC and AU is shown in figure 1.

Figure 1 ACSC and AU contact information

ACSC	**Air University**
ACSC Director of Research Maxwell AFB, AL 36112 DSN: 493-8886 Comm: 334-953-8886	Chief, Institutional Effectiveness Air University 55 LeMay Plaza South Maxwell AFB, AL 36112 DSN: 493-4166 Comm: 334-953-4166

Step 2: Complete Collaborative Institutional Training Initiative (CITI) Training

CITI training is a subscription service which provides research ethics training to investigators and researchers. The USAF pays the subscription fee for the required ethics training for IRB submission therefore you will be required to complete the on-line training prior to submission of your protocol. There are two required core courses that are required and an additional seven courses to complete CITI training. The website for CITI training is found at the following URL: www.citiprogram.org. The following requirements apply to this training:

a. Individuals wishing to conduct human research must complete investigator training
b. Training requirements are determined by the IRB named on the Assurance
c. All AF IRBs utilize the Collaborative Institutional Training Initiative (CITI)
d. Contact your IRB before logging onto CITI to ensure you take the correct training modules

Step 3: Contact the appropriate IRB representative

It is important that you coordinate with the POC for the IRB to which you are applying. Your goal may be to get what is called an exempt or an expedited review. An exempt or expedited review procedure consists of a determination of human subjects research made by the IRB chair or administrator upon submission of the protocol in accordance with the requirements set forth in 45 CFR 46.110 and 21 CFR 56.110. The most significant requirement for this consideration is that the protocol must be determined as minimal risk. The activities that are listed in 45 CFR 46.110 and 21 CFR 56.110 should not be construed as meeting the requirements of minimal risk. The inclusion on the list simply indicates that the protocol *may* be eligible for review through the expedited review procedures. There are also other criteria that must be met to qualify for exempt or expedited review. The rules for meeting these criteria are found in 32 CFR 219.101b. The research criteria for an expedited review can be found on the OHRP website at http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm. Wright Patterson Air Force Base is the primary IRB center for ACSC. The following IRB representatives are included in figure 2.

Figure 2 WPAFB IRB POC

Wright Research Site IRB	*POC*
AFRL/HEH *2245 Monahan Way* *Wright-Patterson AFB, OH 45433* *DSN 785-0311* *Commercial: (937) 255-0311* *DSN Fax: 674-8119* *Commercial: (937) 904-8119*	***AFRL Institutional Review Board*** *711 HPW/IR* *2245 Monahan Way, Bldg 29* *Wright-Patterson AFB OH 45433-7008* *(937) 656-4995*

There are six alternative IRB's found in Figure 3.

Figure 3 Other IRB centers

AF Academy *Gail Rosado* *719-333-6593* *Gail.Rosado@usafa.af.mil*	***AF Research Lab*** *WPAFB, OH* *Lt Douglas C. Grafel* *937-656-5437* *Douglas.Grafel@wpafb.af.mil*
David Grant Medical Center *Travis AFB, CA* *Rebecca Austria* *707-423-7263* *Rebecca.Austria02@travis.af.mil*	***Keesler AFB*** *Randi Byrd* *228-377-7926* *Randi.Byrd@keesler.af.mil*
Malcolm Grow Medical Center *Andrews AFB, MD* *Cheryl James* *240-857-8745* *Cheryl.James-02@andrews.af.mil*	***Wilford Hall Medical Center*** *Lackland AFB, TX* *Rachel Montez* *210-292-4683* *Rachel.Montez@lackland.af.mil*

It is highly recommended that you visit the WPAFB IRB website at http://www.wpafb.af.mil/library/factsheets/factsheet.asp?id=7496 and download the most recent information required since changes to the IRB process occur. The WPAFB IRB website includes such topics and links to the IRB membership, regulations, assurance of compliance, forms and templates, training, history and philosophy, related links, international research requirements, quality assurance, FAQs, and contact information.

Step 4: IRB Submission Requirements

The following documents (with URL in parenthesis) are required for submission of a research protocol to the IRB:

- Directorate cover letter (http://www.wpafb.af.mil/shared/media/document/AFD-070227-028.doc). The directorate cover letter is a memorandum signifying that the proposal meets all ethical requirements including qualifications of investigators, peer review of

protocol, relevance to the USAF, need for human subjects testing, along with personnel and resources required to complete the research.

- Principal Investigator (PI) cover letter (http://www.wpafb.af.mil/shared/media/document/AFD-070227-035.doc). The PI cover letter is a memorandum for the AFRL IRB requesting division and IRB review and approval of the protocol. The PI ensures that the human research conforms to the written, approved document, monitors progress of the research, notifies the IRB if risk or benefit is substantially different from the approved protocol, notifies the IRB if there is any conflict of interest, provides progress and final reports to the IRB and ensures informed consent documents meet AFRLI 40-402.
- Protocol (http://www.wpafb.af.mil/shared/media/document/AFD-070227-037.doc and Protocol writing instructions (http://www.wpafb.af.mil/shared/media/document/AFD-070227-038.doc). Detailed electronic protocol instructions are available to complete the protocol as required by the IRB. An example of the protocol is provided in Appendix A.
- Informed consent document. Provides subjects a formal document indicating what the risks of the particular protocol, what is the purpose of the research, how the information will be used and the subjects rights.
- Curriculum Vita for all investigators which for IRB's is often limited to two pages and specifically must focus on your education and research and publication history.
- Assurance (http://www.wpafb.af.mil/shared/media/document/AFD-070917-026.doc) where applicable) The letter of assurance is a federal requirement based on 32 Code of Federal Regulations (CFR), Part 219 which provides protection for human subjects including the definitions of "research" and "human subject", additional DoD component-specific requirements and component-specific definitions, for example, for defining "engaged". This DoD Assurance document is for use only by non-DoD institutions

The following checklist is provided to assist you in assembling your protocol package:

Link to Investigator Submission Checklist

(http://www.wpafb.af.mil/shared/media/document/AFD-080604-062.pdf)

Step 5: Determine required personnel.

Certain personnel will be required in order to complete your application. These include:

- Medical monitor: This person may not have to be a physician but it is recommended that they be a licensed medical professional. You may check with your IRB POC to verify if you are required to have a physician present during your protocol testing or if the IRB licensed physician will co-sign any non-physician medical professional.

- Safety monitor: This person ensures that all safety precautions are met and that Material Safety Data Sheets (MSDS) are available along with ensuring compliance with all hazards and hazardous materials.
- Statistician: Utilization of the Spaatz/XA program assistant or other ACSC/C personnel who have degrees related to statistics may meet this requirement. Please check with your IRB POC.
- Branch Chief: It is possible that the branch and division chief are met by the Director of Research at AU. Again, check with your IRB POC for protocol requirements.
- Division Chief: For AU, the Director of Research will be the division chief.

Step 6: Proposal submission

Obtain all personnel signatures involved in your research proposal and submit your application. The requirement for submission of your proposal is that it must be full and complete. Utilize the IRB checklist to verify all required documentation. Original signatures will be required. Although this author attempted to have the IRB proposal reviewed prior to submission, it was strongly discouraged by the IRB. Remember that the IRB will usually meet only once per month so you will need to submit as soon as possible. You will have 60 days to complete all required materials, however, it is best to submit them all together to ensure the IRB receives all required documents. All required documents should be available on-line at the IRB website or through the IRB POC. The goal of the IRB submission is to provide specific data required by the IRB to determine if the proposed protocol meets all DOD and Federal regulations regarding IRB human subject requirements.

This completed IRB protocol should include the IRB checklist, division cover letter, principle investigator cover letter, protocol, informed consent, assurance documentation, CITI training and curriculum vita. An example of an IRB proposal has been included as Attachment 1.

Attachment 1: IRB Checklist

All Requirements are due within 60 days of submission to the IRB
Submission Date_____ Suspense Date_____
Protocol #
Protocol Name: ACSC EEG Baseline Assessment
Principal Investigator: Maj (Dr.) David F. Tharp

Requirement	Completed	Notes
Division cover letter		From the sponsoring AFRL Division
PI cover letter		Signed by the Principal Investigator
Protocol (with attachments)		See Protocol Writing Instructions
Informed consent document		See ICD Writing Instructions
Assurance Documentation		
CITI training for investigators		
CV for all investigators		2 Pages or less, list education, experience, and brief summary of publications.
International Only:		
Certified back translation ICD		

Division Cover Letter

MEMORANDUM FOR 711 HPW/IR (AFRL IRB)

FROM: AFRL/DIRECTORATE OR OTHER ORGANIZATION

SUBJECT: ACSC EEG Baseline Assessment

1. The undersigned have reviewed the proposed research and affirm that it meets all requirements for ethical human experimentation as set forth in current Federal, DoD, Air Force, and AFRL guidance.

2. Specifically, we confirm that the proposed research meets the following criteria:

a. The investigators are fully qualified to carry out the proposed research and understand the duties required by AFRLI 40-402.

b. The proposal has undergone adequate peer review to ensure its scientific quality.

c. The research is relevant to valid Air Force needs.

d. The required information can only be obtained by use of human subjects.

e. The experimental/statistical design is adequate to resolve the hypothesis or answer the research question. Every effort has been made to minimize the number of human subjects required to achieve the required statistical strength.

f. As required, any laboratory or other facility has undergone adequate safety inspection.

g. The medical consultant understands the duties contained within AFRLI 40-402, paragraph 1.6. and is fully prepared to respond to medical emergencies. Every effort has been made to minimize and the discomfort and risk to which each subject will be exposed.

3. The personnel and resources required to implement the proposed research are currently available to the proposing organization. It is the organization's intent to carry out this research as approved.

4. The funding source for this research is (check one): □ Program 6 (S&T)
□ Program 8 (Medical) X Other (Specify). None required.

5. For questions or concerns, please contact the principal investigator at XXX-XXXX.

Terry Bentley/Dr.
Statistical Consultant

John Mansuy/Maj
Medical Consultant

Ed Oullette/Maj
System Safety Engineer

David Tharp/Maj
Program Manager

Brett Morris/Col
Director
Director of Research
Air Command and Staff College
Maxwell AFB, AL 36112

26 Oct 2000

MEMORANDUM FOR AFRL IRB

FROM: ACSC 21STUS

SUBJECT: Principal investigator cover letter for **ACSC EEG Baseline Assessment**

1. Request division and IRB review and approval of the protocol named above which should be considered as a freestanding protocol.

2. As principal investigator, the undersigned affirms that the protocol complies with the requirements for human experimentation set forth in Federal code and the DoD, Air Force, and AFRL instructions implementing it. In addition, the undersigned agrees to:

a) Ensure that all human research conducted under this protocol will conform to the written, approved document, including any restrictions imposed during the approval process.

b) Read and abide by the assurance of compliance with the federal policy for the protection of human subjects [e.g., a DoD Single Project Assurance, AFRL's Multiple Project Assurance (MPA #50002) or a Federal Wide Assurance] provided by the undersigned's institution to cover activities conducted under this protocol.

c) Monitor the progress of this research and notify the IRB in writing within 24 hours of any unexpected event or medical misadventure.

d) Notify the IRB, in a timely manner, if either the risk or the benefit of the research appears substantially different from those represented in the protocol, or if early results clearly resolve the hypothesis.

e) Notify the IRB in writing of any conflict of interest (financial or otherwise) within the research team that exists or arises during the project.

f) Provide progress and final reports for research as required by the IRB as well as notifying the IRB of any publications resulting from this protocol.

g) Ensure that the originals and copies of the signed Informed Consent Document for all subjects are filed as required by AFRLI 40-402 and that all records of completed research are provided to the IRB administrator for permanent archiving.

David F. Tharp/Maj/Dr
Principal Investigator

Protocol:

ACSC EEG Baseline Assessment

F-WR-2007-0000-H

1. **Principal Investigator**

   David F. Tharp/Maj/Dr., ACSC/21 STUS, DSN: XXX-XXXX

2. **Associate Investigators**

   a. Brett Morris/Col/Dr., ACSC/21 STUS, DSN: XXX-XXXX

3. **Medical Consultant or Monitor**

   John Mansuy/Maj/MSN, ACSC/21STUS DSN: XXX-XXXX

4. **Facility/Contractor**

   The facility will be isolated to one room at Air Command and Staff College. It will contain all of the EEG equipment and a free standing computer system. The equipment used for EEG baseline assessment will be the Deymed 10/20 EEG system.

5. **Objective**

   The purpose of this research is to create a normative EEG database for ACSC in order to compare and contrast future research experiments. There are currently at least 4 different databases used for comparison analysis: Dr. Robert Thatcher's Neuroguide, Dr. E. Roy Johns' NxLink, Neuro Data, Inc., Neuroscience, Inc.

6. **Background**

   The rationale for creating the EEG database using ACSC students is that there is currently no baseline data using this subset of the population. ACSC students are unique in that they have been selected as some of the "best and brightest" the Air Force has to

offer. They provide a mid-level career baseline by which future research can be compared. The EEG brainwaves of ACSC in-residence folks have never been studied and yet statistically, there is a high probability that many of these folks will go on to be general officers.

7. Impact

There is no current normative baseline research using EEG. The AF has previously utilized EEG research with test pilots and other human subjects research, however, there is no baseline EEG to compare results. Having a normative database by which to compare future research will help in assessing the efficacy of new research such as that found in neurofeedback.

8. Experimental Plan

a. Equipment: The equipment used to assess EEG is produced by the Deymed Corporation. Deymed produces state-of-the-art medical grade equipment that assesses EEG. The cap used on the subjects head uses 19 separate electrodes that are placed on the surface of the scalp to collect brainwave activity. The cap and electrodes are non-invasive and use the 10/20 arrangement system. Neuroprep is used to clean the hair and scalp of naturally produced body oils and Electrogel is used to increase connectivity and decrease impedance. Both Neuroprep and Electrogel are medical standard grade materials that comply with industry regulations for medical use and have MSDS sheets indicating appropriate use.

b. Subjects:

The total number of subjects will be 100. The inclusion criteria are Air Command and Staff College Air Force field grade officers (0-4). Exclusions include International students at ACSC and other sister service students (Army, Navy, Marine, Coast Guard). No other exclusions apply. The population will be the same students as listed above in the subjects section. The male/female ratios will depend on the number of volunteers. No age range will be required or exempted. No special subjects (45 CFR 46 subparts B-D) will be involved. No compensation will be offered to the subjects. The only qualifications required are to be enrolled at ACSC and the time commitment will be 1.0 hours. The 1.0 hours will include 15 minutes for paperwork including signed release, 15 minutes of setup for the EEG, 15 minutes for EEG assessment and 15 minutes for clean-up). No screening for subjects or special tests will be required. Recruitment procedures will include an announcement at ACSC to the general assembly notifying potential subjects of the study. Requirements include being an ACSC student and will include both male and female subjects with no age restrictions. The subjects will be completely voluntary and will include the first 100 subjects who are willing to participate. The recruitment of subjects will be by the principal investigator, Maj Tharp and no coercion or undue influence will be tolerated. This will be minimized by explaining the purpose of the study. This will include vital information such as the study being completely voluntary, confidential and that it will not help or hinder any academic issues related to ACSC. No posters, fliers or e-mails will be disseminated or utilized.

c. Duration:

1 hour. This will include 15 minutes for paperwork, 15 minutes of setup for the EEG, 15 minutes for EEG assessment and 15 minutes for clean-up.

d. Description of experiment, data collection, and analysis:

This proposal only includes data collection. EEG Data collection will be completed using the DEYMED system. A headmap using an Electrocap with sensors is placed on the head, Electrogel is inserted into the 19 small holes in the cap using an applicator similar to a syringe that will not protrude the skin. The Electrogel is inserted into the holes between the cap and the scalp and is a non-invasive measure. The DEYMED system collects EEG data similar to the concepts used in EKG. The person will then be asked to close his/her eyes for six minutes while baseline EEG data is recorded. Then, they will be asked to open their eyes for six minutes (allowing for blinking) while data is again recorded. Once completed, the Electrocap will be removed and the Electrogel will be cleaned off the subject using a small amount of water and a towel. The program manager maintains security access to the encrypted data using an unidentifiable numbering system. No personal identifying information will be requested or maintained. The raw EEG data will be stored in the computer under two separate locking mechanisms. One is the computer password and the second is the numbering encryption system. This computer will also be secure when not in use via a locked door with access only to the program manager, the division chair and the medical liaison.

e. Safety monitoring:

This is a low-risk study. The principal investigator was the CEO of his practice where EEG data was routinely collected on more than 100 subjects. Similar data was also collected and used at his primary work environment at the Federal Bureau of Prisons. There have been no adverse reactions to the Electrogel out of approximately 250 subjects

measured using this system. No immediately available monitor will be necessary for this study

f. Confidentiality protection:

Storage of data will be limited to one stand-alone computer. The EEG data will be transferred directly to the DEYMED system which has no memory capabilities to a stand-alone computer. For security measures, the data will be encrypted using an encrypted numbering system. The computer information will also be password protected and the computer will be kept under lock and key when not in use. There will be no personal identification information requested or kept. The information will be kept for a minimum of seven years but will most likely be kept indefinitely as it will be used as a baseline measure. No hard copy or electronic files will be removed from the facility or stored in a non-secure manner.

9. Risk Analysis

There are no known associated risks in the literature or in the experience of the primary investigator. The only known side effect is a temporary, cutaneous reaction that is resolved after cleansing the area with water. There is no known, long term or permanent effects from the Electrogel.

10. References

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11. **Attachments**
    a. Informed Consent Document
    b. Curriculum vita of investigators
    c. Other attachments if applicable, such as letters of collaborative support, contractor assurances, and any other supportive documentation.

INFORMATION PROTECTED BY THE PRIVACY ACT OF 1974

Informed Consent Document
For
ACSC EEG Baseline Assessment

ACSC/21 STUS, Air University, Maxwell AFB, AL

Principal Investigator: David F. Tharp/Maj/Dr., ACSC/21 STUS, DSN: XXX-XXXX

Associate Investigators: Brett Morris/Col/Dr., ACSC/DER, DSN: XXX-XXXX

1. **Nature and purpose:** You have been offered the opportunity to participate in the "ACSC EEG baseline assessment" research study. Your participation will occur at Air University

   The purpose of this research is to create a baseline for which future research can be measured. In current research with EEG, there are at least 4 different databases used for assessing EEG: Neuroguide, NxLink, Neuro Data, Inc., and Neuroscience, Inc. The most widely used is Dr. Robert Thatcher's Neuroguide database. This database is made up of 625 individuals from the general population. What is not currently available is a baseline database for a population of United States Air Force personnel. Specifically, field grade officers that are considered in the top 20 percent based on their acceptance to Air Command and Staff College (in-residence IDE JPME).

   The time requirement for each volunteer subject is anticipated to be a total of one visit of approximately one hour each. A total of approximately 100 subjects will be enrolled in this study.

2. **Experimental procedures:** If you decide to participate, EEG Data collection will be completed using the DEYMED system. A headmap using an Electrocap with sensors is placed on the head, Electrogel is inserted into 19 small holes in the cap using an applicator similar to a syringe that will not protrude the skin. The Electrogel is inserted into these holes between the cap and the scalp and is a non-invasive measure. The DEYMED system is turned on to collect EEG data very similar to the concepts used in EKG. You will be asked to close your eyes for 6 minutes while baseline EEG data is being recorded. Then, you will be asked to open your eyes for 6 minutes (allowing for blinking) and again data is recorded. Once this is complete, the Electrocap is removed and the Electrogel is cleaned off the subject using a small amount of water and a towel.

3. **Discomfort and risks:** There are no known associated risks in the literature or in the experience of the primary investigator. The only known side effect is a temporary, cutaneous reaction that is resolved after cleansing the area with water. There is no known, long term or permanent effects from the Electrogel.

4. **Precautions for female subjects or subjects who are or may become pregnant during the course of this study:** If you are female or if you are pregnant, or may become pregnant during the course of this study, you must read and sign the Briefing Addendum for Female Subjects prior to making a decision to consent to become a subject in this research study.

5. **Benefits:** You are not expected to benefit directly from participation in this research study.

6. **Compensation:** If you are active duty military, you will receive your normal active duty pay.

7. **Alternatives:** Choosing not to participate is an alternative to volunteering for this study.

8. **Entitlements and confidentiality:**

    a. Records of your participation in this study may only be disclosed according to federal law, including the Federal Privacy Act, 5 U.S.C. 552a, and its implementing regulations and the Health Insurance Portability and Accountability Act (HIPAA), and its implementing regulations, when applicable, and the Freedom of Information Act, 5 U.S.C. Sec 522, and its implementing regulations when applicable. Your personal information will be stored in a locked cabinet in an office that is locked when not occupied. Electronic files containing your personal information will be password protected and stored only on a secure server. It is intended that the only people having access to your information will be the researchers named above and this study's Medical Monitor or Consultant, the AFRL Wright Site IRB, the Air Force Surgeon General's Research Compliance office, the Director of Defense Research and Engineering office or any other IRB involved in the review and approval of this protocol. When no longer needed for research purposes your information will be destroyed in a secure manner (shredding). Complete confidentiality cannot be promised, in particular for military personnel, whose health or fitness for duty information may be required to be reported to appropriate medical or command authorities. If such information is to be reported, you will be informed of what is being reported and the reason for the report.

    b. Your entitlements to medical and dental care and/or compensation in the event of injury are governed by federal laws and regulations, and that if you desire further information you may contact the base legal office (ASC/JA, 257-6142 for ACSC). In the event of a research related injury, you may contact the medical monitor, John Mansuy/Maj, of this research study at DSN: XXX-XXXX.

    c. If an unanticipated event (medical misadventure) occurs during your participation in this study, you will be informed. If you are not competent at the time to understand the nature of the event, such information will be brought to the attention of your next of kin or other listed emergency contact.

        Next of kin or emergency contact information:

        Name_____ Phone#_____

d. The decision to participate in this research is completely voluntary on your part. No one may coerce or intimidate you into participating in this program. You are participating because you want to. Maj David Tharp, or an associate, has adequately answered any and all questions you have about this study, your participation, and the procedures involved. Maj Tharp can be reached at DSN XXX-XXXX. Maj Tharp, or an associate will be available to answer any questions concerning procedures throughout this study. If significant new findings develop during the course of this research, which may relate to your decision to continue participation, you will be informed. You may withdraw this consent at any time and discontinue further participation in this study without prejudice to your entitlements. The investigator or medical monitor of this study may terminate your participation in this study if she or he feels this to be in your best interest. If you have any questions or concerns about your participation in this study or your rights as a research subject, please contact Lt Col Michael Richards at DSN XXX-XXXX.

e. No Personal Identifiable Information will be obtained for this study. Signing this document in no way alters your ability to obtain medical treatment that is not part of this study. Any Private Health Information obtained in the course of this study may be used by the investigator unless you revoke authorization to do so *in writing.* If your data is disclosed by the investigator to one of the parties listed above, those parties may pass on your data without further notification to you. Data collected in the course of this study may be withheld from you by the investigator for the duration of the study. If withheld, your data will be released at the conclusion of the study.

f. Your participation in this study will not be photographed, filmed or audio/videotaped. Any release of records of your participation in this study may only be disclosed according to federal law, including the Federal Privacy Act, and the Freedom of Information Act, 5 USC 522, and its implementing regulations. This means personal information will not be released to unauthorized source without your permission. These recording may be used for presentation or publication, with your signed permission. They will be stored in a locked cabinet in a room that is locked when not occupied. Only the investigators of this study will have access to these media. They will be maintained for a minimum of seven years.

YOU ARE MAKING A DECISION WHETHER OR NOT TO PARTICIPATE. YOUR SIGNATURE INDICATES THAT YOU HAVE DECIDED TO PARTICIPATE HAVING READ THE INFORMATION PROVIDED ABOVE.

Volunteer Signature_____Date_____

Volunteer Name (printed)_____

Advising Investigator Signature _____ Date _____

Investigator Name (printed)_____

Witness Signature _____Date _____

Witness Name (printed)_____

We may wish to present some of the video/audio recordings from this study at scientific conventions or use photographs in journal publications. If you consent to the use of your image for publication or presentation in a scientific or academic setting, please sign below.

Volunteer Signature_____Date_____

Privacy Act Statement

Authority: We are requesting disclosure of personal information. Researchers are authorized to collect personal information on research subjects under The Privacy Act-5 USC 552a, 10 USC 55, 10 USC 8013, 32 CFR 219, 45 CFR Part 46, and EO 9397, November 1943.
Purpose: It is possible that latent risks or injuries inherent in this experiment will not be discovered until sometime in the future. The purpose of collecting this information is to aid researchers in locating you at a future date if further disclosures are appropriate.
Routine Uses: Information may be furnished to Federal, State and local agencies for any uses published by the Air Force in the Federal Register, 52 FR 16431, to include, furtherance of the research involved with this study and to provide medical care.
Disclosure: Disclosure of the requested information is voluntary. No adverse action whatsoever will be taken against you, and no privilege will be denied you based on the fact you do not disclose this information. However, your participation in this study may be impacted by a refusal to provide this information.

Curriculum Vita

The Curriculum Vita (CV) should be two pages in length maximum as recommended by the IRB. There are three key components of the CV that should be included: education, experience and a brief summary of publications. For most researchers, the challenge will be to condense your information into two pages.

The educational section should be concise listing school, degree, dates attended, accreditation (if any), dissertation or thesis title, and any significant awards.

The experience section is the one that is the most difficult to reduce. This author would recommend actually completing the third requirement (brief summary of publications) prior to completing the experience section as this will then help determine how much information can be placed in the experience section. Once you know how much space you have allotted, provide the title, date, and major job accomplishments, especially as it relates to the IRB. Discuss briefly any research completed, which will help assure the folks on the IRB that you are competent, ethical and professional.

The publications section should include your most recent publications first. Provide in recommended format (most likely APA). Two different types of examples are included:

Morris, B. (Fall 2008). Book Review: *Talking to the Enemy: Track Two Diplomacy in the Middle East and South Asia* (Santa Monica, Calif.: RAND, 2007), by Dalia Dassa Kaye. *Air Power History*, Vol. 55, 3.

Fox, D., Tharp, D.F., Fox, L.C. (2005). Neurofeedback: An alternative and Efficacious Treatment for Attention Deficit Hyperactivity Disorder. Applied Psychophysiology and Biofeedback, 30(4) 365-373.

APPENDIX A[1]

IRB MEMBERSHIP

The AFRL Wright Site Institutional Review Board (IRB) has approximately 20 members. It is composed of a mix of men and women, including Air Force officers, enlisted personnel and civilians with the following backgrounds:

Flight surgeon (physician)
Lawyer
Chaplain
Physicist
Psychologist
Biomedical Engineer
Systems Safety Engineer
Medical Technician
Local officials

At ACSC, the local officials required will include at minimum a medical consultant (who does not have to be a physician and whose credentials should be coordinated with the appropriate IRB), a statistician (who usually is a person on staff at ACSC), a safety consultant (ACSC has a designated safety person), a Branch Chief and Division Chief. At ACSC, the Branch Chief and Division Chief can be dual-hatted and is the ACSC Director of Research. These folks will be signing your IRB proposal so it is best to get them on board as soon as possible. They will most likely also want to review your proposal and want specific details about what is expected of them. Be as clear and detailed with them as possible to avoid any confusion.

APPENDIX B[2]

REGULATIONS

21 CFR 50 Protection of Human Subjects

(http://www.access.gpo.gov/nara/cfr/waisidx_04/21cfr50_04.html)

21 CFR 56 Protection of Human Subjects

(http://www.access.gpo.gov/nara/cfr/waisidx_04/21cfr56_04.html)

32 CFR 219 Protection of Human Subjects

(http://www.access.gpo.gov/nara/cfr/waisidx_99/32cfr219_99.html)

AFI 36-2601 Air Force Personnel Survey Program (http://www.e-publishing.af.mil/shared/media/epubs/AFI36-2601_USAFASUP1.pdf)

AFI 40-402 Protection of Human Subjects

(http://www.wpafb.af.mil/shared/media/document/AFD-070319-050.pdf)

AFRLI 40-402 Using Human Subjects in Research, Development, Test, and Evaluation

(http://www.wpafb.af.mil/shared/media/document/AFD-070514-027.pdf)

DoD Directive 3216.2 (http://www.wpafb.af.mil/shared/media/document/AFD-070514-028.pdf)

10 USC 980 Limitations On Use Of Humans as Experimental Subjects

(http://www.wpafb.af.mil/shared/media/document/AFD-070319-052.pdf)

APPENDIX C[3]

IRB ASSURANCE OF COMPLIANCE

What is an Assurance?

An Assurance of Compliance is a formal written, binding agreement that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved. The AF assurance is a signed agreement between the institutional official of an institution engaged in Air Force sponsored research and HQ AF/SGRC which assures that all research will be performed according to the requirements of AFI 40-402 (http://www.fas.org/irp/doddir/usaf/afi40-402.pdf), 32 CFR 219 (http://www.dtic.mil/biosys/downloads/32cfr219.pdf) and 10 United States Code 980.

What is research and when does an institution become engaged in research?

"An institution becomes 'engaged' in human subjects research when its employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes." See 32 CFR 219.102(d), (f) (http://www.dtic.mil/biosys/downloads/32cfr219.pdf). Also, see OHRP definition of Engagement in Research: http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm

Who has to have an assurance? Do contractors and their subcontractors have to have an assurance?

32 CFR 219.103 (http://www.dtic.mil/biosys/downloads/32cfr219.pdf). Assuring compliance with this policy--research conducted or supported by any Federal Department or Agency. Each

institution engaged in research which is covered by this policy and which is conducted or supported by a federal department or agency shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in this policy.

How does my institution get an Air Force Assurance of Compliance?

The following templates may be used to apply for an Assurance of Compliance:

For Institutions that already have a Federal Wide Assurance with OHRP, an Addendum to the Federal Wide Assurance (http://www.wpafb.af.mil/shared/media/document/AFD-070917-024.pdf) will be required.

For Non-DoD Institutions that do NOT have a Federal Wide Assurance, you must attain one by visiting the following site: http://www.hhs.gov/ohrp/assurances/assurances_index.html.

In addition you will also need to complete a DoD addendum for the above FWA which can be found in the forms and templates section of our site.

In either case, an Air Force IRB is required to review and approve any Human Subjects Research that is sponsored by the Air Force. A Research Review Agreement designates the AFRL Wright-Site IRB as an IRB authorized to review research for your institution. This document is required with the submission of both the FWA Addendum and the Non-DoD Assurance applications.

These agreements are scoped, meaning an institution may select to apply the Assurance and/or the Research Review Agreement to one research protocol, a selected group of protocols or all

research occurring at an institution. However, selecting any option other than a single research protocol will require prior coordination through HQ USAF/SGRC.

If you are a DoD institution, please contact the IRB directly, as these forms will not apply.

How long does it take to get a Federal Wide Assurance?

After the signed paperwork is submitted to OHRP, it takes about 1 week to process.

Will any Assurance do and who gets to determine what an acceptable Assurance is?

AFI 40-402 3.1 (http://www.dtic.mil/biosys/downloads/32cfr219.pdf). Assurances. All human research conducted or supported by the Air Force shall be conducted under an Assurance of compliance acceptable to the Air Force, unless the research is exempt from these regulations under 32 CFR 219.101(b) (http://www.dtic.mil/biosys/downloads/32cfr219.pdf). A DoD Assurance is required for research performed at DoD facilities and funded by the DoD. A DoD Assurance issued by the Air Force is required for research conducted by the Air Force at an Air Force facility. Any changes to an Assurance covering research conducted or supported by the Air Force must be prospectively approved by HQ AF/SGRC.

Who approves DoD/Air Force Assurances?

AFI 40-402 3.1.1 (http://www.dtic.mil/biosys/downloads/32cfr219.pdf). Applications for DoD Assurances issued by the Air Force must be reviewed and approved by HQ AF/SGRC prior to initiation of any human research.

What about non Air Force Assurances issued by other Federal Departments?

AFI 40-402 3.1.4 (http://www.dtic.mil/biosys/downloads/32cfr219.pdf). Non-Air Force Assurances. In most cases, a DoD Assurance will be required. However, in some cases, HQ AF/SGRC may accept an Assurance issued by DHHS. Whenever the Air Force accepts an Assurance not issued by the Air Force, the institution must provide a separate written assurance that it will comply with requirements unique to the Air Force, including this instruction and all attachments, and that it will report to the Air Force continuing compliance and safety issues, such as continuing reviews, adverse events, and protocol deviations, in accordance with this instruction.

Are there contractor-specific regulations?

AFI 40-402 4.1 (http://www.dtic.mil/biosys/downloads/32cfr219.pdf). Contractor Studies. This section sets out procedures for contracted research involving the use of human subjects. An organization may not award a contract for research involving the use of human subjects until the requirements of this instruction have been fully met.

AFI 40-402 4.1.4. The Air Force will not award a contract involving a human subject to an individual unless he or she is affiliated with or sponsored by an organization that can, and does, assume responsibility for that subject.

AFI 40-402 4.1.5. Any organization applying for a contract to conduct research involving a human subject must provide a written assurance that it will abide by the policy for protection of human subjects as stated in this instruction.

APPENDIX D[4]

IRB FORMS AND TEMPLATES

All forms linked here are either in Microsoft Word format (.doc) or PDF (.pdf).

Addendum to the Federal Wide Assurance Instructions (.doc) 79 kb
(http://www.wpafb.af.mil/shared/media/document/AFD-070917-023.doc)

Addendum to the Federal Wide Assurance Template (.pdf) 490 kb
(http://www.wpafb.af.mil/shared/media/document/AFD-070917-024.pdf)

Adverse Event Report (.doc) 58 kb
(http://www.wpafb.af.mil/shared/media/document/AFD-070227-027.doc)

AF-DoD Assurance for Non-DoD Institutions Instructions (.doc) 75 kb
(http://www.wpafb.af.mil/shared/media/document/AFD-070917-026.doc)

AF-DoD Assurance for Non-DoD Institutions Template (.pdf) 680 kb
(http://www.wpafb.af.mil/shared/media/document/AFD-070917-027.pdf)

Amendment Request (.doc) 34 kb
(http://www.wpafb.af.mil/shared/media/document/AFD-070227-040.doc)

Directorate Cover Letter (.doc) 56 kb
(http://www.wpafb.af.mil/shared/media/document/AFD-070227-028.doc)

Exempt Request (.doc) 41 kb
(http://www.wpafb.af.mil/shared/media/document/AFD-070227-039.doc)

Final Report Template (.doc) 57 kb
(http://www.wpafb.af.mil/shared/media/document/AFD-070227-029.doc)

Guidelines for Assurances (.pdf) 60 kb
(http://www.wpafb.af.mil/shared/media/document/AFD-081007-024.pdf)

HIPAA Authorization Form (.doc) 49 kb
(http://www.wpafb.af.mil/shared/media/document/AFD-070227-034.doc)

HIPAA Waiver Form (.doc) 36 kb
(http://www.wpafb.af.mil/shared/media/document/AFD-070227-033.doc)

ICD Instructions (.doc) 66 kb

(http://www.wpafb.af.mil/shared/media/document/AFD-070227-030.doc)

ICD Template (.doc) 49 kb
(http://www.wpafb.af.mil/shared/media/document/AFD-070227-031.doc)

Individual Investigator Agreement (.doc) 24 kb
(http://www.wpafb.af.mil/shared/media/document/AFD-080604-064.pdf)

IRB Presentation Instructions (.doc) 24 kb
(http://www.wpafb.af.mil/shared/media/document/AFD-070227-032.doc)

Principal Investigator Cover Letter (.doc) 58 kb
(http://www.wpafb.af.mil/shared/media/document/AFD-070227-035.doc)

Protocol Writing Instructions (.doc) 71 kb
(http://www.wpafb.af.mil/shared/media/document/AFD-070227-038.doc)

Protocol Writing Template (.doc) 50 kb
(http://www.wpafb.af.mil/shared/media/document/AFD-070227-037.doc)

Progress Report Template (.doc) 61 kb
(http://www.wpafb.af.mil/shared/media/document/AFD-070227-036.doc)

Research Review Agreement Instructions (.doc) 62 kb
(http://www.wpafb.af.mil/shared/media/document/AFD-070917-028.doc)

Research Review Agreement Template (.pdf) 702 kb
(http://www.wpafb.af.mil/shared/media/document/AFD-070917-029.pdf)

Submission Checklist (.pdf) 49 kb
(http://www.wpafb.af.mil/shared/media/document/AFD-080604-062.pdf)

APPENDIX E[5]

IRB TRAINING

This course is suitable for investigators and staff conducting research with human subjects at the Air Force Research Laboratory (AFRL) and for investigators and staff at other sites conducting Research, Development, Testing, and Evaluation (RDT&E) activities with human subjects. This training is an annual requirement. For those that have already taken the initial training, the instructions for refresher training are located at the bottom of the page.

Initial Training

1. Log on to the CITI site: https://www.citiprogram.org/default.asp
2. Click on "New Users Register Here".
3. Under "Participating Institutions" select "Air Force Research Laboratory"
4. Establish your username and password.
5. Enter your name
6. Enter e-mail address
7. Click submit
8. At a minimum enter gender and highest degree
9. Under "Which course do you plan to take?" select "Basic Human Subjects - Biomedical & Social & Behavioral Focus"
10. Under "Role in Human Subject Research" select "Principal Investigator" if appropriate or "Co-Investigator" otherwise.
11. Enter office phone
12. Click submit

13. When asked "Is this your first time taking a CITI course at Air Force Research Laboratory?" click the first option "Yes, This is my first time. Please take me to the AFRL BASIC Course." If you have never completed a CITI IRB course.

14. Click submit

15. Click "No" when asked if you want to affiliate yourself with another organization

16. When asked whether or not you would like to take the HIPAA Course, select "Yes" if you are participating in research that requires either a HIPAA Waiver or Authorization; otherwise, select "No".

17. To begin the training, click "enter" about half way down the next page under the "status" column heading.

18. When you are finished, print your certificate and maintain a personal copy.

Annual Refresher Training

1. Go to https://www.citiprogram.org/default.asp

2. Log on with your username and password.

Note: The screen will display Air Force Research Laboratory. Under "My Courses", it will say "Basic/Refresher Course - Human Subjects Research". You can enter the training under "Status". Now, if you see a long list of modules, it is the basic course, not the refresher course.

3. Click on "**Add a course or update your learner groups for Air Force Research Laboratory**".

4. Click "Update Groups".

Note: Under Question 1, click "No" and "I need to complete the AFRL Refresher Course".

5. Click "**Submit**" at the bottom of the page.

6. Click "**Go Back to Learner's Main Menu**".

7. The tab will still say "**Basic/Refresher Course**" but once you click on it there will be fewer modules and you will see "**Refresher Course 101 Introduction**".

8. When you are finished, print your certificate and maintain a personal copy.

APPENDIX F[6]

IRB HISTORY AND PHILOSOPHY

The Belmont Report (http://www.wpafb.af.mil/shared/media/document/AFD-070227-046.pdf)

The Declaration of Helsinki (http://www.wpafb.af.mil/shared/media/document/AFD-070227-047.pdf)

The Nuremberg Code (http://www.wpafb.af.mil/shared/media/document/AFD-070227-048.pdf)

APPENDIX G[7]

RELATED LINKS

American Society for Bioethics and Humanities (http://www.asbh.org/)

Centers for Disease Control and Prevention (http://www.cdc.gov/)

U.S. Department of Health & Human Services (http://www.os.dhhs.gov/)

U.S. Food and Drug Administration (http://www.fda.gov/)

U.S. Air Force Medical Service Human Subject Protection (https://kx.afms.mil/kxweb/dotmil/kj.do;jsessionid=474A1F56F948E3E6C41B3BE80FCC3B17?functionalArea=HumanSubjectProtection)

The Institutional Review Board Discussion and News Forum (http://www.irbforum.org/)

National Institutes of Health (http://www.nih.gov/)

The President's Council on Bioethics (http://www.bioethics.gov/)

Office for Human Research Protections (http://www.hhs.gov/ohrp/)

Public Responsibility in Medicine and Research (http://www.primr.org/)

APPENDIX H[8]

INTERNATIONAL RESEARCH REQUIREMENTS

IRB review and approval of international research involves a number of challenges. These procedures apply to both minimal and greater than minimal risk research. The IRB must ensure that the proposed research is acceptable in the local setting where it is to be conducted. Local community/ethical concerns, subject population, institutional policies and values must be taken into account along with the country's and any local laws regarding human use research.

Because the AFRL Wright Site IRB may not be able to be fully aware of the local research context, human use research that is to be conducted in a country other than the United States must be reviewed and approved by an IRB or similar body in the country where the research will take place. The institution engaged in research must designate this IRB and document such a designation per the Research Review Agreement, which can be found in the "Forms & Templates" section. The agreement delineates the authorities of the local IRB and the WRS IRB and assures the appropriate level of review is taking place. Documentation of the overseas IRB's approval must be provided in writing to the WRS IRB.

Also, because overseas research frequently involves a contract (normally through EOARD or AOARD) to do the research, the PI or local Program Manager must ensure that the appropriate Assurance of Compliance is filed for the protocol, please refer to the "Assurance of Compliance" section. The assurance ensures that any overseas research investigators along with the contracted company, university, etc., understand and will abide by human use ethical guidelines, as well as DoD and Air Force Regulations concerning human use research.

Finally, a Directorate Cover Letter must be submitted along with the protocol, certifying that the organization sponsoring the research and the AOARD or EOARD Program Manager, if

applicable, approve of the project. The PI Cover Letter should come from the Principal Investigator listed on the protocol, who is directly engaged in research with the subjects.

All overseas, non-exempt research will be reviewed by the Full WRS IRB.

International Exempt Requests

Because of the concerns of local research context as discussed above, any Request for Exemption for research that is going to be carried out overseas must also be reviewed, and found to be exempt by an IRB or similar body in the country in which that research will take place. Written certification of the exemption should be provided to the WRS IRB with the Exemption Request.

All overseas exempt research will be forwarded to HQ USAF/SGRC.

APPENDIX I[9]

QUALITY ASSURANCE

What documents do I need to have on file for a Quality Assurance (QA) visit?

- Approved version of your protocol
- A disk or CD with an electronic, read-only copy of your final approved protocol
- SGHARP approval letter (for greater than minimal risk research)
- IRB approval letter
- Approved Assurance of Compliance (if applicable)
- Approved informed consent document (ICD)
- All signed ICDs
- CITI (or equivalent) training certificate of all primary and associate investigators recruitment measures/advertising
- Subject screening forms (if applicable)
- Research data questionnaires (if applicable)

An audit form (http://www.wpafb.af.mil/shared/media/document/AFD-070228-007.xls) will be used during your quality assurance visit. You can use it to help prepare for the visit and for periodic self-inspection.

The QA visit typically consists primarily of documentation review. You MUST have all informed consent properly obtained and documented. This means that every subject enrolled in the study has a signed ICD that matches the IRB-approved version and is dated **after** the date of the written IRB protocol approval.

Always store information protected by the Privacy Act in a locked cabinet in a room that is locked at the end of the day. In general, this includes data such as social security numbers, medical screening information, and audio or videotape recordings.

The results of the QA visit are discussed with each PI informally during and at the end of the visit. At the end of the visit you will be offered a copy of the signed audit form for your records. Results of each QA visit will be presented to the IRB at the monthly convened meeting for

review and approval. Once the IRB has reviewed and approved the audit, you will receive the results in writing. The letter will list findings, recommendation and required actions.

Findings and recommendations are provided for your information in an effort to improve compliance with human use regulations. Required actions represent a deficiency that must be corrected. All required actions must be completed within 14 days of receipt of your QA letter.

The goal of QA visits is to improve or maintain your compliance as a researcher and further your understanding of the IRB and its requirements. It is meant to be a friendly and informative process. We welcome any feedback or questions regarding the process at any time.

Audits of active research are required per AFI 40-402 2.6.12.

APPENDIX J[10]

FREQUENTLY ASKED QUESTIONS

What are all of these regulations? Which ones do I need to know?
There are 5 main regulations that you should be familiar with and need to follow when using human subjects in research:

- 32 CFR 219, Protection of Human Subjects (Federal Level)
- DoDD 3216.2, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research (DoD Level)
- AFI 40-402, Protection of Human Subjects in Biomedical and Behavioral Research (Air Force Level)
- 10 USC 980, Limitation on Use of Humans as Experimental Subjects
- AFRLI 40-402, Using Human Subjects in Research, Development, Test, and Evaluation (AFRL policy on human subjects)

Two other commonly used regulations are 21 CFR 50 and 21 CFR 56, which are FDA regulations that apply primarily when conducting new drug or new medical device research.

What happens to my protocol when I submit it to the IRB?
Formal review of your protocol will not occur until all submission requirements have been received by the IRB. All new protocols are first read by the IRB administrator and chairperson. The protocol will then be sent back to you for revision before it is sent to all of the IRB members; Suggested or required changes will be in the form of comments in the right margin and changes tracked. Please address all comments and accept changes if you agree with them. Discussion of changes with the chairperson is encouraged as it is important that you understand why certain changes are being required. Your protocol will then be sent to all of the IRB members one week prior to the meeting. If your protocol is reviewed through expedited procedures, it will be processed for approval once you have adequately addressed comments and questions.

Once I submit a protocol, how long will it take to get approved?
For a protocol that requires review by the Air Force Surgeon General's office of Research Compliance (SGRC) you can generally expect to wait 4-6 weeks after IRB approval for full approval of your research (see below for information on when you can begin collecting data). After IRB approval, the protocol is reviewed by our legal office and signed off on by the AFRL Institutional Official (IO). It is then forwarded to SGRC for review and approval. Changes to your protocol may be requested by both the IRB and SGRC. Your timeliness in completing these changes will impact the overall review time for your protocol.

How will I know if my protocol has to go to SGRC for review?
All protocols are reviewed by SGRC. If it is a greater-than-minimal risk protocol, or you have an Assurance of Compliance that requires approval, your protocol will have to be sent to SGRC for approval. In addition, international research and non-lethal weapons research must also be approved by SGRC.

Once the IRB has approved my protocol, when can I start recruiting and enrolling subjects and collecting data?
If it is a minimal risk protocol, research may begin once you receive **written** approval from the IRB. If your protocol requires an Assurance of Compliance, it must be approved by SGRC before the IRB can provide approval. If it is a greater-than-minimal risk protocol, you must have full SGRC **written** approval in addition to written IRB approval prior to starting.

What should I do if I suspect an adverse event has occurred?
Refer to the guidelines for reporting adverse events on the AFRL IRB home page. Do not hesitate to contact the medical monitor listed on the protocol or the IRB chairperson to discuss details regarding a suspected adverse event.

What if I am only a day late for the protocol submission deadline?
Any protocols submitted after the close of business four weeks prior to the IRB meeting will be added to the following month's agenda. There are exceptions to this rule for "just in time" research or extenuating circumstances.

What documents do I need to have on file for a quality assurance visit?

- Approved version of your protocol
- A disk or CD with an electronic, read-only copy of your final approved protocol
- SGRC approval letter
- IRB approval letter
- Approved assurance of compliance (if applicable)
- Approved informed consent document (ICD)
- All signed ICDs
- CITI (or equivalent) training certificate of all primary and associate investigators Recruitment measures/advertising
- Subject screening forms (if applicable)
- Research data questionnaires (if applicable)

I have an international research protocol to submit. What special considerations should I make and what can I expect?
When writing the protocol several issues should be considered. The important factors to consider are local culture and community, primary language of the subjects, and ensuring that there is a local advocate for research subjects to contact. The protocol must be reviewed and approved by a local IRB (or other ethics committee) where the research is to be conducted. The WRS IRB also requires that the ICD be written in the local language and that an English translation be provided.

The rest of the requirements, as outlined in the Submission Checklist are the same. As such, an Assurance of Compliance must be completed for the institutions engaged in research, and a Research Review Agreement must be completed by the institution, where a local IRB is designated.

Research that may be considered "exempt" in the United States may not be considered as such in

overseas settings or by overseas IRBs. It is important to have approval of exemption from an IRB or equivalent in the country where your research will take place when submitting an overseas request for exemption to our IRB.

What should I do when I get comments from the SGHARP regarding my protocol?
After your protocol is approved as a greater-than-minimal risk study by the IRB, it is forwarded to the Surgeon General's Human and Animal Research Protections Committee (SGHARP) for review. SGHARP is part of SGRC. You may receive an email from the IRB administrator after your protocol has been reviewed by the SGHARP. Please respond in writing (email) to each of the comments made by the SGHARP. If, in the process of addressing concerns from the SGHARP, you amend or change your protocol, please attach it to your email response.

What are the 3 different levels of review conducted by an IRB?
Exempt, Expedited and Full Board Review.

Who determines if my research protocol is exempt, expedited or requires full board review?
This determination is made by the *IRB chair or administrator* upon submission of your research protocol. First, your proposal must be considered ***minimal risk*** to qualify for exemption or expedited review. There are certain additional criteria that your research must meet to be considered exempt or to qualify for expedited review. The rules for exempt research are delineated in 32 CFR 219.101(b). The criteria for research that qualifies for expedited review can be found on the OHRP web site at:
http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm.

What if my research is exempt; am I finished?
It depends; once you receive a letter from the IRB that approves your request for exemption from human use regulations, there are no further requirements unless there is a change in the research that affects human subjects. ***Your proposal is still considered to be human research and you have an obligation to protect human subjects' rights and minimize risks.*** You must notify the IRB if there is a change in the design of your experiment that affects human subjects, otherwise no further reports or actions are required.

What if my research is reviewed by expedited procedures, do the same requirements apply as a full board review?
Yes. The only difference between expedited and full board review is that your protocol is reviewed by only one person versus the entire convened IRB. Typically, but not always, these reviews take less time to approve since they are conducted in a rolling fashion (as soon as we receive your protocol and all submission requirements, we review it). All of the same rules and regulations for full board reviewed research apply to expedited research.

Are there any additional requirements for survey research?
Yes. In addition to IRB approval, your survey must be routed through AFPC and be assigned a Survey Control Number (SCN). This process can sometimes take several months. A SCN will not be required for IRB submission, but WILL BE REQUIRED for final IRB approval unless your proposal is exempt. Therefore, you can submit your survey to the IRB for exemption or review while you are awaiting a SCN from AFPC. If your proposal is considered exempt, a SCN

will not be required by the IRB. However, you still need to obtain approval for your survey/interview from AFPC per AFI 36-2601 Air Force Personnel Survey Program. Please note that these reviews are completely separate functions.

I don't understand how to address comments and changes requested by the IRB?
Reviewing a revised protocol from the IRB will require a working knowledge of the reviewing functions in Microsoft Word, specifically Comments and Tracking Changes. Comments can be viewed in the right margin of the revised protocol that is sent back to you. These comments are usually in the form of a question or a requirement for additional information. You can answer these by adding another comment or simply inserting the answers directly into the protocol where required and tracking your changes so that the IRB can view your response. Suggested changes entered by the IRB must either be accepted or declined by you. If you agree with the change, simply right click on it and choose "accept insertion." If you disagree with the change then provide a justification for why in the form of an inserted comment. Tracked changes will be colored and underlined.

What if I do not get all the required materials for continued review submitted on time?
Any approved protocol must be reviewed by the IRB ***at least every 365 days***. If continued review and IRB approval is not conducted and documented within this timeframe, IRB approval of the protocol will be suspended and all subject recruitment, enrollment, data collection and analysis must stop. Research can only be resumed after written IRB approval is obtained. In order to prevent this from happening as much as possible, we review protocols on an 11 month cycle.

Is my proposed project even human research?
In order for a project to be considered human research it must meet the definition of both "research" and "human subject" as defined below from 32 CFR 219.102:
Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.
Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:
(1) Data through intervention or interaction with the individual, or
(2) Identifiable private information.

How often is human subjects training required for investigators?
Annually. If investigator training is not completed on an annual basis it may result in the suspension of IRB approval for current research or inability to submit new research to the IRB.

Are there any rules or guidelines on how subjects can be recruited?
Federal regulations consider direct advertising for study subjects to be the start of the informed consent and subject selection process. All advertising must be reviewed and approved by the IRB as part of the package for initial review. The IRB reviews the information contained in the recruiting material (ads, flyers, emails, briefings, etc.) and the mode of its communication to determine that the recruiting procedures are not coercive. The protocol should contain sufficient

detail on the recruiting procedures - who will do the recruiting, when and how it will be done -to allow this determination to be made.

Special attention to preventing coercion must be addressed in the protocol when recruiting military subjects. It must be made clear that commanders and supervisors will not be involved in the recruiting process in any way. Personnel in a position of authority should not promote participation or be present during subject recruiting briefings nor should they be made aware of who does and does not volunteer.

Generally, any advertisement to recruit subjects should be limited to the information the prospective subjects need to determine their eligibility and interest. The AFRL Wright Site IRB therefore requires that advertisements be limited to the following information:

- The name and address of the clinical investigator and/or research facility.
- The condition under study and/or the purpose of the research.
- In summary form, the criteria that will be used to determine eligibility for the study.
- A brief list of participation benefits, if any (e.g., a no-cost health examination).
- The time or other commitment required of the subjects.
- The location of the research and the person or office to contact for further information.

When reimbursement will be provided to subjects, it can be stated in the advertisement that subjects will be compensated for time, travel and inconvenience. However, dollar amounts are not permitted in the advertising/recruiting material.

Glossary

ACSC	Air Command and Staff College
AFI	Air Force Instruction
AFRL	Air Force Research Laboratory
AFRLI	Air Force Research Laboratory Instruction
AU	Air University
CFR	Code of Federal Regulations
CITI	Collaborative Institutional Training Initiative
IRB	Institutional Review Board
EEG	Electroencephalography
QEEG	Quantitative Electroencephalography
WPAFB	Wright Patterson Air Force Base

Notes

[1] WPAFB IRB website
[2] Ibid
[3] Ibid
[4] Ibid
[5] Ibid
[6] Ibid
[7] Ibid
[8] Ibid
[9] Ibid
[10] Ibid

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